K093911

Edwards

JAN 21 2010

510(k) Summary

Submitter:	Edwards Lifesciences, LLC One Edwards Way Irvine, CA 92614-5686
Contact Person:	Patricia A. Milbank Vice President, Clinical and Regulatory Affairs
Date Prepared:	December 17, 2009
Trade name:	Fogarty Occlusion Catheter
Regulatory Number:	21CFR 870.4450
Classification Name:	Vascular Occlusion Balloon Catheter Catheter, Intravascular Occluding, Temporary
Regulatory Class:	Class II
Product Code:	MJN
Predicate Device:	Fogarty Occlusion Catheter, Pre-amendment Device
Device Description:	The Fogarty Occlusion Catheter is indicated for temporary vessel occlusion. The catheter consists of a single-lumen polyvinylchloride catheter body with a latex balloon at the distal end and a gate valve at the proximal end. The catheter lumen is used for inflation of the balloon via a syringe connected to the gate valve. The device is supplied sterile and for single use only. This Special 510(k) is submitted for clearance of changes to the packaging of the predicate device.
Intended Use:	The Fogarty Occlusion Catheter is intended for temporary vessel occlusion.
Comparative Analysis:	The Fogarty Occlusion Catheter with its modified packaging has been demonstrated to be substantially equivalent to the predicate device.
Functional/Safety Testing:	The Fogarty Occlusion Catheter has successfully undergone functional testing demonstrating equivalence to the predicate device.
Conclusion:	The changes to the packaging for the Fogarty Occlusion Catheter are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 21 2010

Edwards Lifesciences, LLC
c/o Patricia A. Milbank
Vice President, Clinical and Regulatory Affairs
One Edwards Way
Irvine, CA 92614-5686

Re: K093911
Fogarty Occlusion Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: December 17, 2009
Received: December 22, 2009

Dear Ms. Milbank:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093911

Device Name: Fogarty Occlusion Catheter

Indications for Use:

The Fogarty Occlusion Catheter is indicated for temporary vessel occlusion.

Prescription Use X **AND/OR** **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093911